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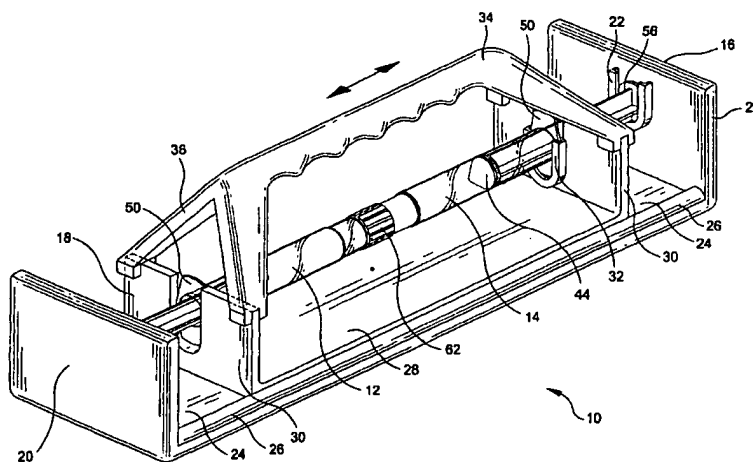
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(54) Title: CEMENT MIXING AND DISPENSING DEVICE



(57) Abstract: An apparatus and method for mixing a liquid component (42) and a powdered component (40) to form a bone filler has first and second syringes (12, 14) each having a barrel (48), a plunger (44) and an exit port (54). The plunger (44) is moveable within the barrel (48) of each syringe (12, 14) along a longitudinal axis of the barrel. An end portion (46) of each plunger extends beyond the end of each barrel when the plunger tip is space from the exit port (54) and can be activated to move the plunger tip (44) toward the exit port. A mechanism (10) for mixing the liquid and powdered components is operatively connected to each of the barrels and plungers of the first and second syringes so that the relative sliding movement of first and second parts (16, 18) of the mechanism simultaneously moves the plungers (44) and barrels of the first and second syringes (12, 14) relative to one another to move the combined liquid and powdered components back and forth between the first and second syringe.

WO 02/058834 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

- 1 -

CEMENT MIXING AND DISPENSING DEVICE

FIELD OF THE INVENTION

The present invention relates to a method and apparatus for dispensing a settable material, such as bone cement. More particularly, it relates to a method and apparatus
5 consisting of two syringes having their nozzles or dispensing ports interconnected so that material may be transferred back and forth from one syringe to the other.

Bone fillers and cements are widely used in dental, maxio-facial and orthopedic applications. Such cements are made by mixing a liquid and powdered component to form a paste which then sets to form a hard cement or filler.

10 BACKGROUND OF THE INVENTION

Such a cement using calcium phosphate is described by Brown and Chow in their reissued U.S. Patents RE 33,161 and RE 33,221 and by Constantz et al. in their patent 5,820,632. Such a cement using polymethyl methacrylate is described in U.S. Patents 4,900,546 and 5,276,070. Mixing devices for these powder and liquid components have been
15 the subject of numerous patents.

The use of two syringes to mix two liquid substances and then dispense the mixture from one syringe is known from U.S. patent 3,700,215 to Hardman et al. This patent illustrates the outlet nozzles of a pair of syringes connected by a coupling. A perforated mixing tube is slidably mounted within the coupling so that depressing the plunger on one
20 syringe drives the liquid contents of that syringe through the tube into the other syringe and simultaneously drives the perforated mixing tube into the other syringe. The plunger of the other syringe is then depressed, causing the contents to be driven back into the first syringe. This process is repeated a desired number of times until the liquid substances are appropriately mixed. This mixing system is unsuitable for transferring an only partially
25 wetted powdered and liquid component from one syringe to another.

U.S. patent 4,743,229 to Chu illustrates a pair of syringes coupled at their outlet nozzles. One of the syringes contains a fibrillar collagen which is injected into the second syringe which contains particulate mineral material. No further mixing is taught.

U.S. patent 5,908,054 to Safabash et al. relates to a pair of syringes coupled by a fluid
30 transfer assembly. A hollow tube is mounted within the syringes and has first and second ends situated within the interiors of the syringes. The tube has openings to permit the flow of fluid to be transferred from the interior of the first syringe to the second syringe. Again, this

- 2 -

design is unsuitable for passing a high viscosity partially mixed granular/liquid material through the tube.

U.S. patent 5,957,166 to Safabash relates to a device similar to that shown in his patent 5,908,054, with the exception that the perforated tube has a pattern of holes wherein the size and spacing is adjusted to provide an uneven fluid distribution within the second syringe. Again, such a device is unsuitable for transferring a viscous mixture from one syringe to another syringe.

U.S. patent 4,551,135 to Gorman et al. relates to a two component mixing syringe having a flared barrel to facilitate to the extrusion of the plastasized mass. U.S. patent 4,046,145 discloses a connector for use in connecting a pair of syringes.

None of the above references disclose a mechanism designed to allow a syringe containing a liquid component to be connected to a syringe containing a powdered component and allowing the liquid to be injected into the powder in the second syringe and then enabling the liquid-powder combination to be injected back into the first syringe. It has been found that the initial injection of the liquid-powder combination back into the first syringe can require more force than can be generated by simply manually depressing the plunger of the second syringe. Consequently, a mechanism has been provided to assist the individual mixing the liquid and powder components in moving the materials back and forth from one syringe to the other over a number of cycles. It has also been found that imparting mechanical energy into the mixture during mixing beyond that inputted by hand mixing increases the final strength of the set material. This is accomplished by repeating the transfer from syringe to syringe for several cycles after wetting.

SUMMARY OF THE INVENTION

A primary object of the present invention is to provide a simple and inexpensive mixing and dispensing device which will enable the mixing of a settable powder and liquid combination by assisting in the movement of the liquid stored in a first syringe into a powdered component stored in a second syringe and then moving the combination back to the first syringe and repeating the transfer over a number of cycles.

It is a further object of the invention to provide a kit containing two syringes, one containing a liquid component and the other containing a powder component which, when mixed, form a settable cement for use in filling bone defects and inducing bone healing.

- 3 -

It is another object of the invention to enable the end to end connection of two syringes and allowing the connected syringes to be placed in a simple mechanism which allows for the mixing of the liquid and powdered components by the repeated transfer of the liquid powder combination from one syringe to the other.

- 5 It is yet an additional object of the invention to move the mixed cement into one syringe, disassembling the two syringes and using the syringe filled with the mixed liquid and powdered components as a dispensing syringe for placing the mixed cement prior to its setting *in vivo* where it sets to form hard bone cement or bone filler.

- These and other objects of the invention are accomplished by an apparatus for mixing
10 a liquid component and a powdered component which includes first and second syringes, each having a barrel with an exit port at a first end and plunger moveable within the barrel along a longitudinal axis of said barrel. Activation of an outer portion of the plunger which extends beyond a second end of the barrel opposite the first end causes the plunger tip to move towards the exit port or nozzle. The first syringe contains a liquid component and the
15 second syringe contains a powdered component. A mechanism for mixing the two components has a part operatively connected to each of the barrels and a part connected to the portion of the plunger on each syringe extending beyond the end of the barrel so that the relative sliding movement of the two mechanism parts simultaneously moves the plungers and the barrels with respect to each other.

- 20 The first part of the mechanism has contact surfaces for contacting the outer portion of the plungers extending beyond the end of each barrel and the second part contacts each barrel portion and supports the same. The first and second parts are slidably moveable with respect to one another in a direction parallel to the longitudinal axis of each barrel. Each barrel has a flange located at a predetermined distance along its length and extending from an
25 outer surface of the barrel for contacting the second part of this mechanism in a manner which prevents axial movement of the barrel with respect to the second part. Likewise, the outer portion of the plungers are captured within the first part of the slide mechanism to prevent relative movement of the plungers with respect to the first part. To mix the cement, the second part slides with respect to the first part of the mechanism such that the plungers
30 remain stationary with respect to the first part with the barrels being moved by the second part relative to the plungers held by the first part. A handle is provided on one of the first or

- 4 -

second parts to enable the individual doing the mixing to generate sufficient force to move the combined liquid and powder components from one syringe to the other.

The first and second parts slide with respect to each other a distance equal to the initial distance between a tip of said plunger facing the exit port and the exit port so that the entire contents of each syringe are transferred from one syringe to the other during each cycle of mixing. In general, once all of the powder component has been wetted by the liquid component, three to five cycles of mixing have been found sufficient to completely mix the cement to a homogenous consistency.

The method for mixing the two component cement includes placing a liquid component in the barrel of a first syringe where the syringe has a moveable plunger and an exit port, both extending along a longitudinal axis of the barrel. Placing a powdered component in the barrel of a second syringe with the syringe again having a moveable plunger and an exit port both extending along a longitudinal axis of the barrel. Then connecting both exit ports of each syringe and transferring the liquid component of the first syringe of the second syringe by activating the plunger of the first syringe. Thereafter, the combined liquid and powdered components are transferred from the second syringe back to the first syringe by activating the plunger in the second syringe and repeating the back and forth transfer between the first syringe and the second syringe until the powder is completely wetted and then at least two additional times and preferably three to five. The syringes are then dissembled with the syringe containing the combined liquid and powdered component being using to dispense the mixture into the body.

While the preferred method of mixing is manual, those skilled in the art could easily develop a powered reciprocating mechanism for simultaneously moving the plungers back and forth within the barrels of the syringes.

These and other objects and advantages of the present invention will become apparent from the following description of the accompanying drawings, which disclose several embodiments of the invention. It is to be understood that the drawings are to be used for the purposes of illustration only and not as a definition of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be performed in various ways and an embodiment will now be described by way of example and with reference to the accompanying drawings in which similar characters denote similar elements throughout the several views:

- 5 -

FIG. 1 shows an isometric view of the slide mechanism of the present invention supporting two syringes for mixing a liquid and a powder component;

FIG. 2 is an exploded isometric view of the mechanism of FIG. 1 showing the coupled syringes prior to insertion into the slide mechanism of the present invention;

5 FIG. 3 and FIG. 4 are elevation views of the first and second syringes of the present invention containing a liquid component and a powder component respectively prior to being coupled;

FIG. 5 is an elevation view of the coupled first and second syringes mounted in the slide mechanism of the present invention;

10 FIG. 6 is an elevation view showing the slide mechanism of the present invention with the dual syringes mounted therein in a position in which the liquid component of the right syringe has been transferred to the left syringe containing the powdered component by movement of the sliding part of the mechanism in a manner which moves the plunger of the right syringe to its exit port;

15 FIG. 7 is an elevation view similar to FIG. 6 in which the slide mechanism is moved to the opposite end so that the plunger of the second syringe has forced the combined liquid and powdered component back into the right syringe; and

FIG. 8 is an elevation view of one of the first or second syringes containing the combined mixed powdered and liquid component ready for dispensing into the body.

20 DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 and 2 there is shown the mixing mechanism generally denoted as 10 capable of enabling the repeated transfer of the components of two syringes 12 and 14 from one syringe to the other. The mixing mechanism 10 has a first part 16 in which a second part 18 is mounted for sliding engagement. First part 16 has a pair of end walls 20 on which receptacles 22 are mounted. In the preferred embodiment, first part 16 includes a bottom surface 24 having a pair of edge rails 26.

25 In the preferred embodiment, second part 18 includes a base 28 and a pair of end walls 30. Base 28 is designed to fit between rails 26 of first part 16 to be guided thereby. Each end wall 30 of second part 18 includes a receptacle 32 similar to receptacle 22, the
30 function of which will be described hereinbelow.

- 6 -

In the preferred embodiment, a handle 34 is adapted to engage second part 18 by means of four legs 36. In the preferred embodiment, each leg 36 includes a slot 38 which is sized to slide over and capture end walls 30 of second part 18.

Referring to FIGS. 3 and 4, there is shown syringes 12 and 14 respectively with syringe 12 containing a powdered component 40 and syringe 14 containing a liquid component 42. Syringes 12 and 14 are normally pre-filled and provided as a kit and are connected together in the operating room when the need for a bone filler or bone cement arises. In the preferred embodiment, each syringe has a barrel 48 and a plunger 44 which has a portion 46 extending beyond the end 47 of barrel 48 of each syringe. At end 47 of barrel 48 of each syringe there is a flange 50 which extends outwardly from the outer surface of each barrel in a direction generally perpendicular to longitudinal axis 52 of each syringe. While the flanges 50 shown in FIGS. 3 and 4 are located at end 47 of each barrel 48, they could just as easily be located intermediate end 47 and exit port 54 of barrel 48. The end of each plunger portion 46 includes an end flange 56 again extending generally perpendicular to the longitudinal axis 52. Prior to use, syringes 12 and 14 include a seal 60 which seals exit port 54 and maintains the sterility of the exit port.

In the preferred embodiment, flange 50 is sized to be captured in receptacles 32 in both end walls 30 of second part 18. Likewise flanges 56 at the ends of plungers 44 are sized to be captured within receptacles 22 mounted on end walls 20 of first part 16. In the preferred embodiment, receptacles 22, 32 are generally U-shaped and made up on an L-shaped flange fixedly attached to the walls 20, 30. The thickness of the L-shape is sized to correspond to the thickness of the flanges 50, 56. Thus, flanges 50, 56 may be easily slid into the flanges in the vertical direction and prevented from horizontal movement with respect to either the first or second parts 16, 18.

As best seen in FIG. 2 syringes 12 and 14 may be connected by any well known connector 62 after the removal of the seals 60. Such connectors are well known such as a standard luer connector female to female which would accept the male exit port or nozzle 60 of each syringe 12, 14. Such luer connectors are readily available such as, for example, from Fisher Scientific.

Still referring to FIG. 2, mixing mechanism 10 is assembled by placing second part 18 within the rails 26 of first part 16. In this position, second part 18 may be slid between ends 20 of first part 16 while being guided by rails 26. The coupled syringes 12 and 14 are placed

- 7 -

in the sliding mechanism by placing flanges 50 within receptacles 32 and flanges 56 within receptacles 22. Handle 34 is then placed over and coupled to second part 18 by placing slots 38 into engagement with the walls 30.

Referring to FIG. 5, there is shown an elevation view of the assembled mechanism containing syringes 12 and 14 prior to the mixing of powdered component 40 and liquid component 42. Prior to mixing the syringes, barrels 48 and the second part 16 are centered with respect to first part 18.

Referring to FIG. 6, there is shown an elevation view of slide mechanism 10 in the position where the liquid component of syringe 14 had been transferred into the syringe 12 with the powdered component. This is accomplished by moving or sliding second part 18 with respect to first part 16 to end wall 20 thereof towards the right of FIG. 6. As can be seen in the preferred embodiment, plungers 44 remain stationary with respect to first part 16 and barrels 48 move with second part 18 so that plunger 44 of syringe 14 moves to exit port 54 thereof. Simultaneously, plunger 44 of syringe 12 moves towards end 47 thereof opposite its exit port 54. The mechanism of course could be made so that the second part remains stationary and the first part and the plungers of each syringe simultaneously move with the movement of first part 16 while second part 18 is held stationary.

Referring FIG. 7, there is shown in elevation slide mechanism 10 of the present invention with the combined liquid and powdered material syringe 12 being forced back into syringe 14 by movement of second part 18 towards the opposite end wall 20 from that shown in FIG. 6. By moving handle 34 and second part 18 towards the left of FIG. 7, plunger 44 of syringe 12 is moved towards exit port 54 thereof, thereby transferring the liquid and powdered components from syringe 12 into syringe 14. As described above, plunger 44 of syringe 14 is moved towards the end 47 of barrel 48 opposite its exit port 54. In the preferred method, this transfer from syringe 12 to syringe 14 back to syringe 12 is repeated for three to five cycles after all of the powder component has been wetted by the liquid component. The wetting may take one or two cycles depending on the liquid to powder ratio. These cycles are accomplished by repeatedly moving handle 34 and first part 18 back and forth from the left end wall 20 to the right end wall 20 of first part 16. After this repeated transfer of materials between the syringes 12 and 14 is accomplished, either syringe 12 or 14 may be utilized to dispense the mixed liquid and powdered components.

- 8 -

Referring to FIG. 8, a standard needle 66 is attached to exit port or nozzle 54 of the selected syringe 12 or 14 and a protective cover 68 is placed thereover to protect the user. The combined material 70 may then be dispensed in a standard manner by manually moving plunger 44 towards the exit port 54 to discharge the material. A needle and protective cover
5 combination is placed on exit port. Cover removed from discharge.

As indicated above, the powdered component can be a calcium phosphate cement, a glass ionomer cement or a powdered polymethyl methacrylate component. The liquid in the case of the calcium phosphate components can either be water or a sodium phosphate solution with the liquid in the methacrylate system being a monomer of methacrylate.
10 Whichever cements are used, the slide mechanism 10 of the present invention allows for the complete mixing of the powder and liquid components and provides sufficient mechanical advantage to allow this to occur.

While several examples of the present invention have been described, it is obvious that many changes and modifications may be made thereunto, without departing from the
15 spirit and scope of the invention.

Although the invention herein has been described with reference in particular to embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other
20 arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

CLAIMS:

1. A method for mixing a two component cement comprising:
placing a liquid component in the barrel of a first syringe, said syringe having
a movable plunger and an exit port extending along a longitudinal axis of said barrel;
5 placing a powdered component in the barrel of a second syringe, said syringe
having a moveable plunger and an exit port extending along a longitudinal axis of said barrel;
connecting the exit ports of each syringe;
transferring the liquid component from the first syringe to the second syringe
by activating said plunger in said first syringe; and
10 thereafter mixing said components by transferring said combined liquid and
powder components from said second syringe back to said first syringe by activating said
plunger in said second syringe and repeating said back and forth transfer between first and
second syringe at least two additional times.
2. The method as set forth in claim 1, wherein said transfer back and forth
15 between said first and second syringes is repeated for at least five cycles.
3. The method as set forth in claim 1, wherein said longitudinal axis of said first
and second syringes are connected in axial alignment.
4. The method as set forth in claim 3, wherein said transfer of liquid and powder
between said syringes is accomplished by placing said connected first and second syringes in
20 a mechanism which forces one plunger of said first and second syringe towards its
corresponding exit port while simultaneously allowing the other plunger to move away from
its corresponding exit port.
5. The method as set forth in claim 4, wherein said mechanism permits both of
said plungers to move equal distances during said repeated transfer to the combine liquid and
25 powder between said first and second syringes.
6. The method as set forth in claim 5, wherein the second part slides with respect
to said first part a distance equal to the distance between a tip of said plunger and the first end
of said syringe prior to said mixing of said liquid and powdered components.
7. The method as set forth in claim 1, wherein one of said syringes is used to
30 dispense said mixed liquid and powdered components into the body.
8. An apparatus for mixing a liquid component and a powdered component
comprising:

- 10 -

first and second syringes each having a barrel with an exit port at a first end and a plunger movable within said barrel along a longitudinal axis of said barrel by the activation of an outer portion of said plunger extending beyond a second end of said barrel opposite said first end said first syringe containing said liquid component and said second
5 syringe containing said powdered component;

a mechanism having a first part operatively connected to each of said barrels and a second part contacting the portion of said plunger on each barrel extending beyond the end of said barrel so that relative sliding movement of the first and second parts of said mechanism produces relative movement of said barrels with respect to said plungers.

10 9. The apparatus as set forth in claim 8, wherein said mechanism comprises a first part having contact surfaces for contacting said outer portion of said plungers extending beyond the end of each barrel and a second part contacting each barrel portion for supporting the same, said first and second parts moveable with respect to one another in a direction parallel to said barrel longitudinal axis.

15 10. The apparatus as set forth in claim 9, wherein each barrel has a flange on an outer surface thereof for contacting said second part of said mechanism in a manner to prevent axial movement of said barrel with respect to said second part.

11. The apparatus as set forth in claim 10, wherein said outer portion of said plungers are captured within first part of said slide mechanism and prevented from relative
20 movement with respect thereto.

12. The apparatus as set forth in claim 11, wherein said first part of said mechanism is stationary and said second part slides with respect to said first part.

13. The apparatus as set forth in claim 12, wherein said second part includes a handle portion to facilitate sliding of said second part with respect to said first part.

25 14. The apparatus as set forth in claim 12, wherein the second part slides with respect to said first part a distance equal to the distance between a tip of said plunger and the exit port of said syringe prior to said mixing of said liquid and powdered components.

15. An apparatus for mixing a powdered component and a liquid component comprising:

30 a first syringe having a barrel containing the liquid component and a moveable plunger extending along a longitudinal axis of the barrel and exit port;

- 11 -

a second syringe having a barrel containing a powdered component and a moveable plunger extending along a longitudinal axis of the barrel and an exit port; and a connector for connecting said exit ports together.

16. An apparatus as set forth in claim 15, further comprising:

5 a means for assisting the movement of said plunger in said second syringe towards said first syringe after said liquid component has been injected therein.

17. The apparatus of claim 16, wherein said means for assisting includes a slide mechanism operatively connected to each of said barrels and contacting the portion of said plunger on each barrel extending beyond the end of said barrel so that sliding movement of
10 the slide mechanism simultaneously moves said plungers in the same direction with respect to said barrels.

18. The apparatus as set forth in claim 17, wherein said slide mechanism comprises a first part having contact surfaces for contacting a surface of the portion of said plungers extending beyond the end of each barrel and a second part contacting each barrel
15 portion for supporting the same, said first and second parts moveable with respect to one another in a direction parallel to said barrel longitudinal axes.

19. The apparatus as set forth in claim 18, wherein each barrel has an outer flange for contacting said second part of said slide mechanism in a manner to prevent axial movement of said barrel with respect to said second part.

20. The apparatus as set forth in claim 19, wherein ends of said plunger are
20 captured within first part of said slide mechanism and prevented from relative movement within respect thereto.

21. The apparatus as set forth in claim 20, wherein said first part of said slide mechanism is stationary and said second part slides with respect to said first part.

22. The apparatus as set forth in claim 21, wherein said second part includes a
25 handle portion to facilitate sliding of said second part with respect to said first part.

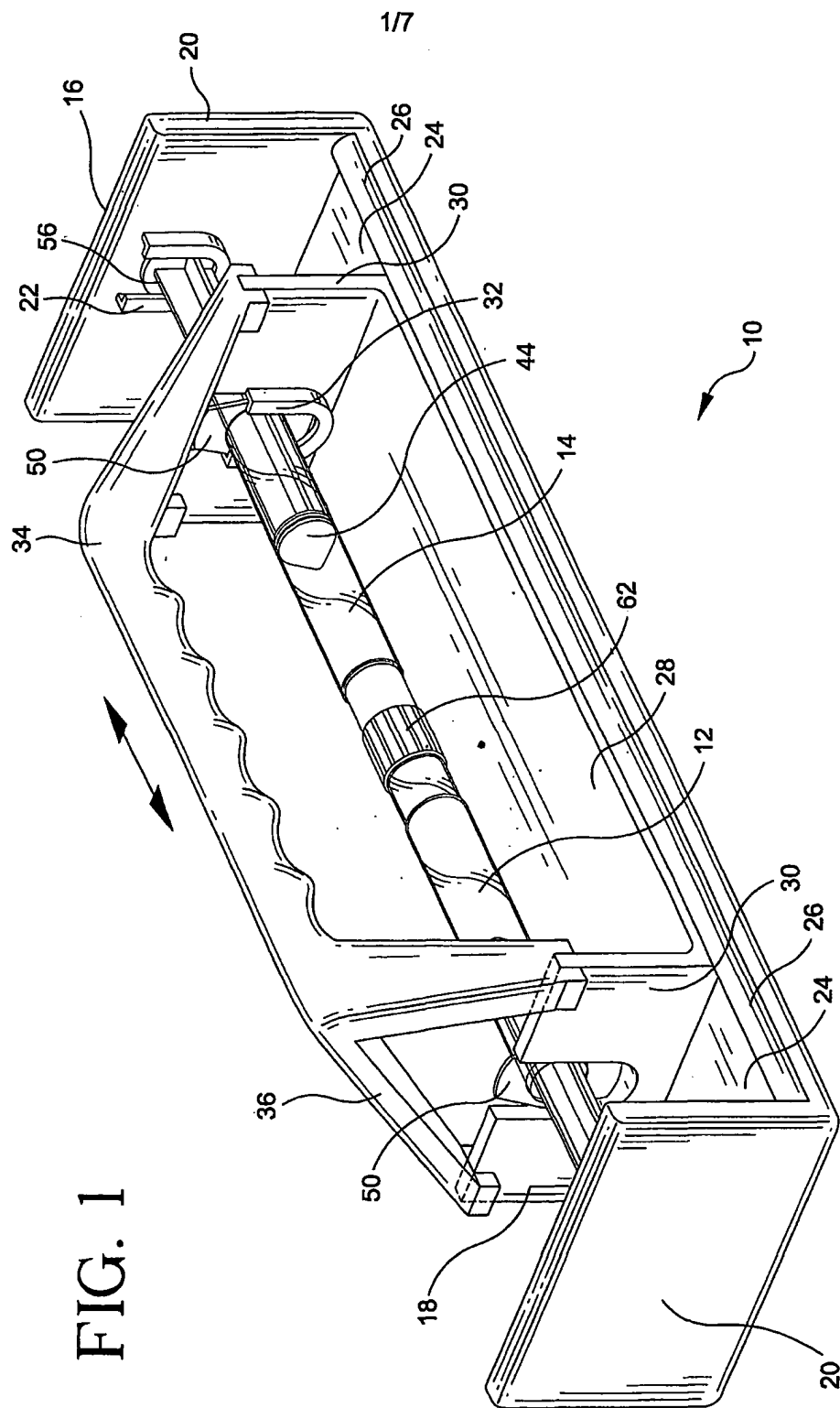


FIG. 1

FIG. 2

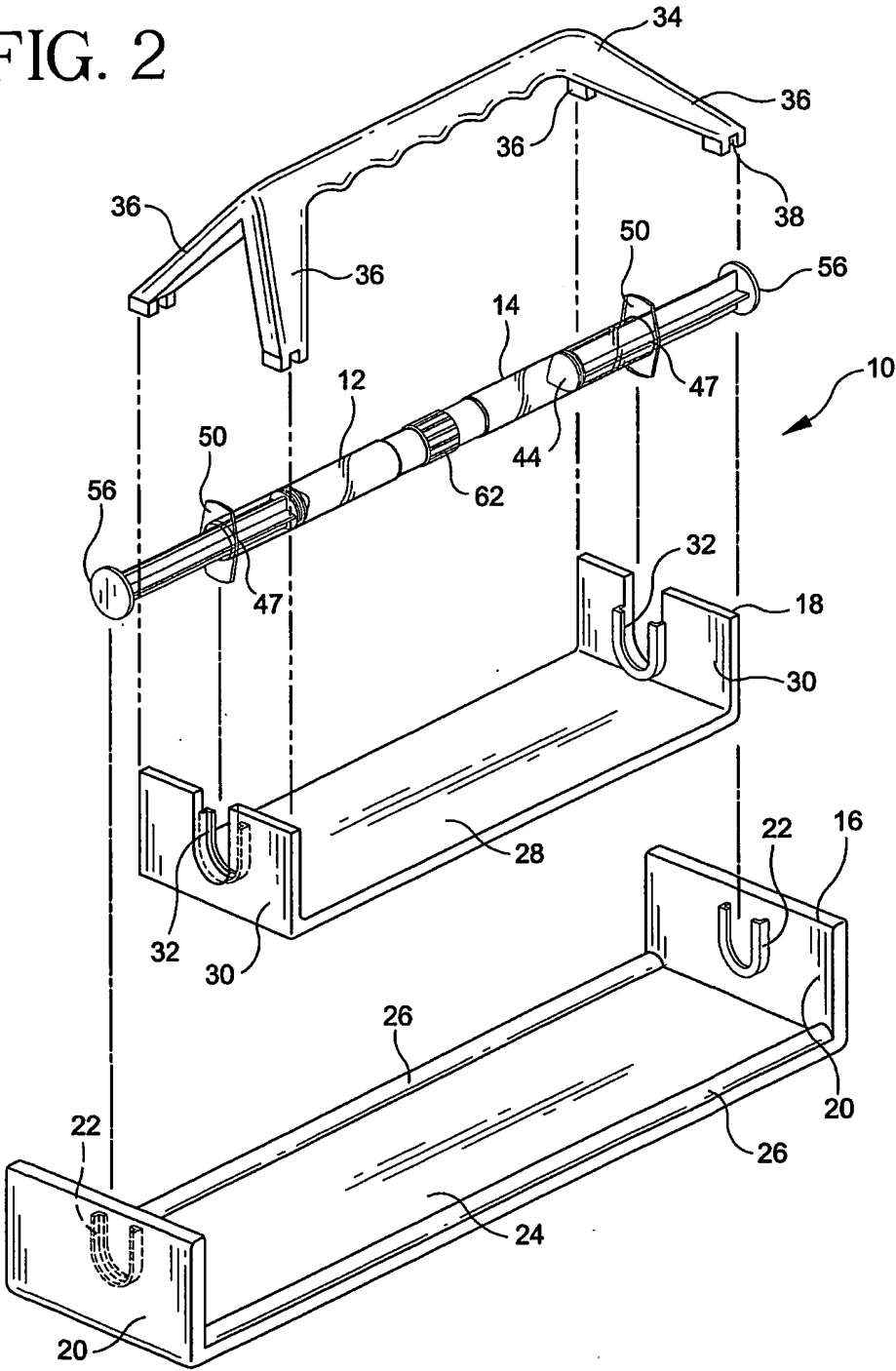


FIG. 3

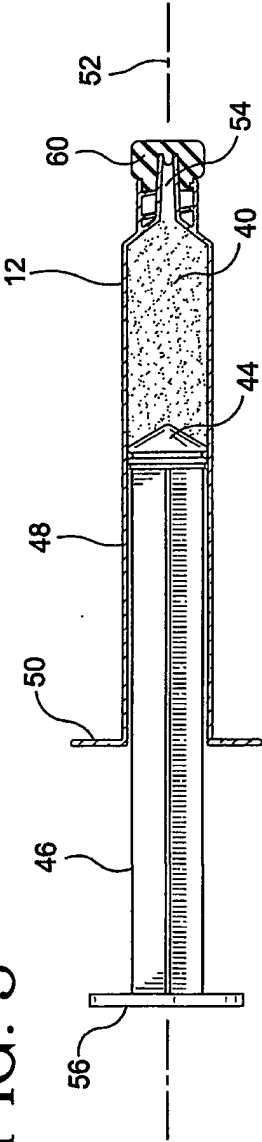
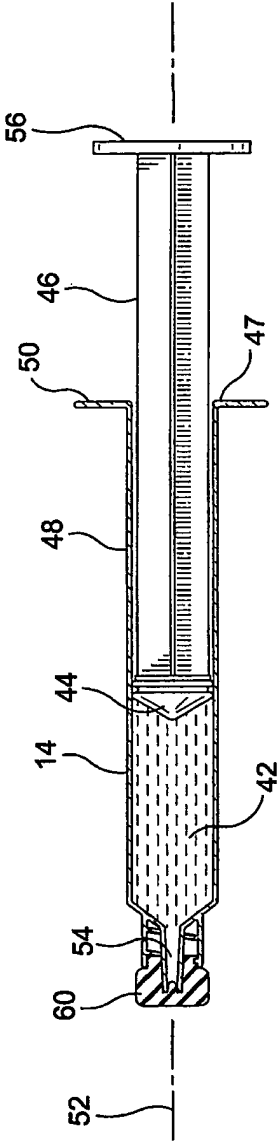
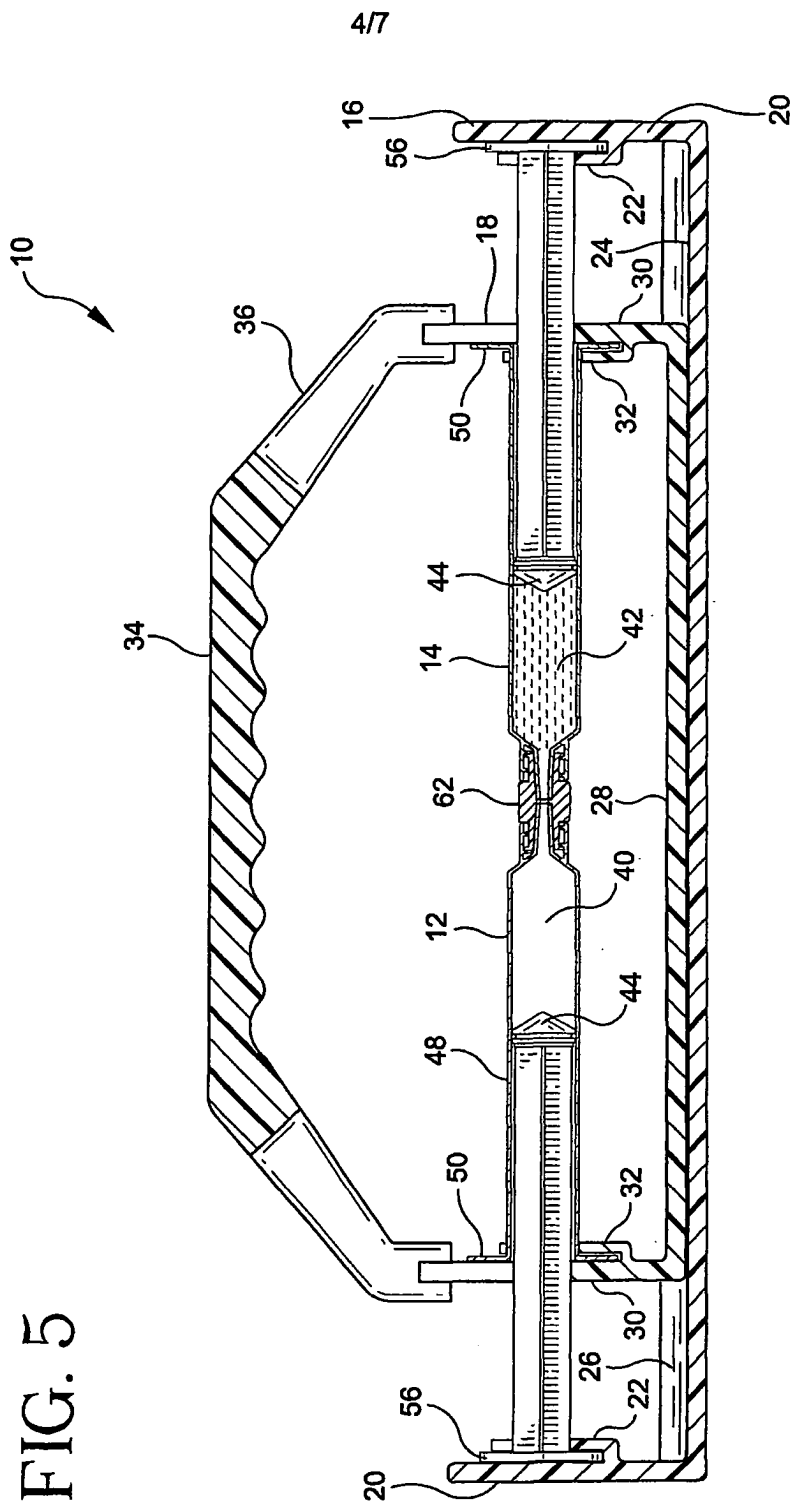
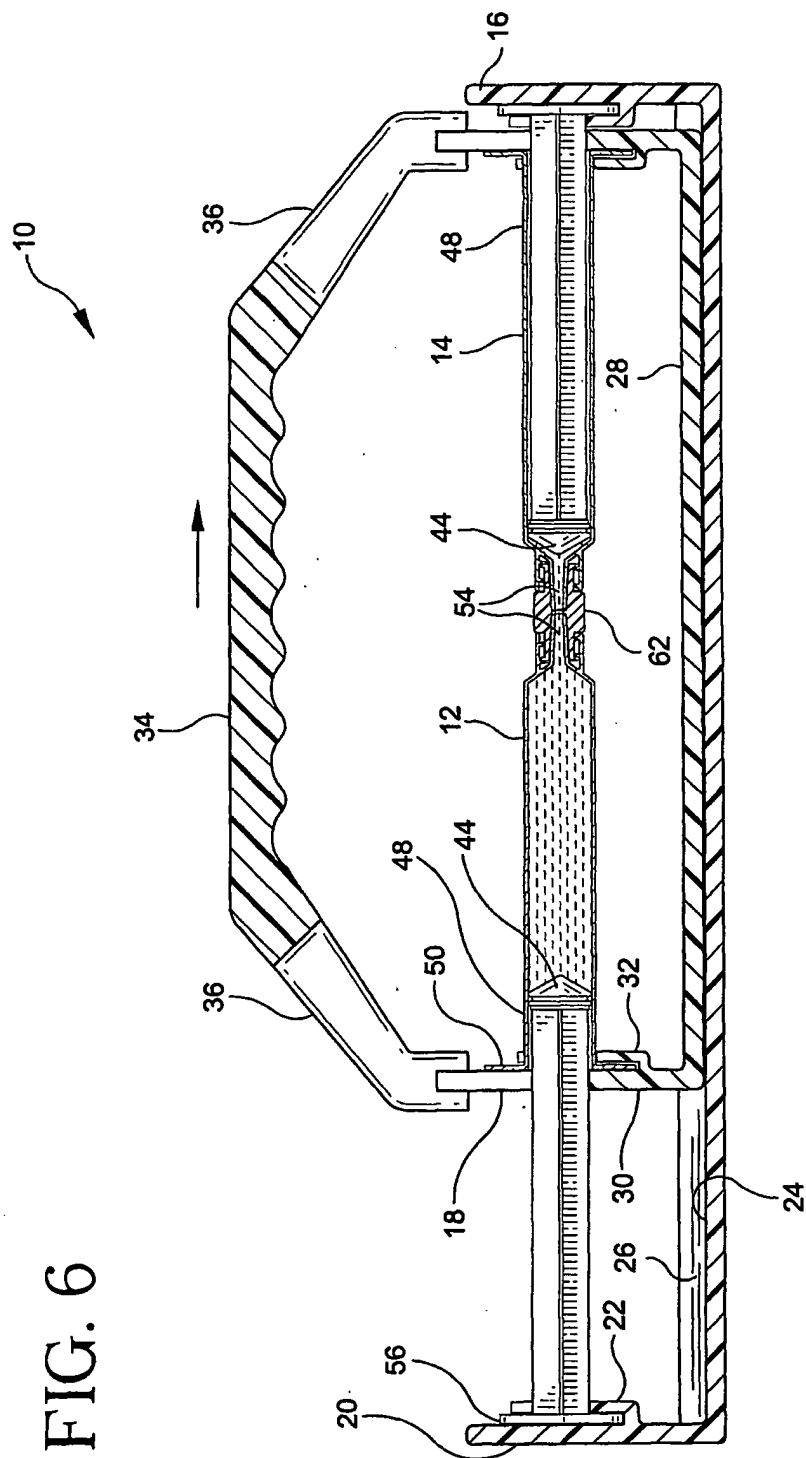


FIG. 4





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FIG. 7

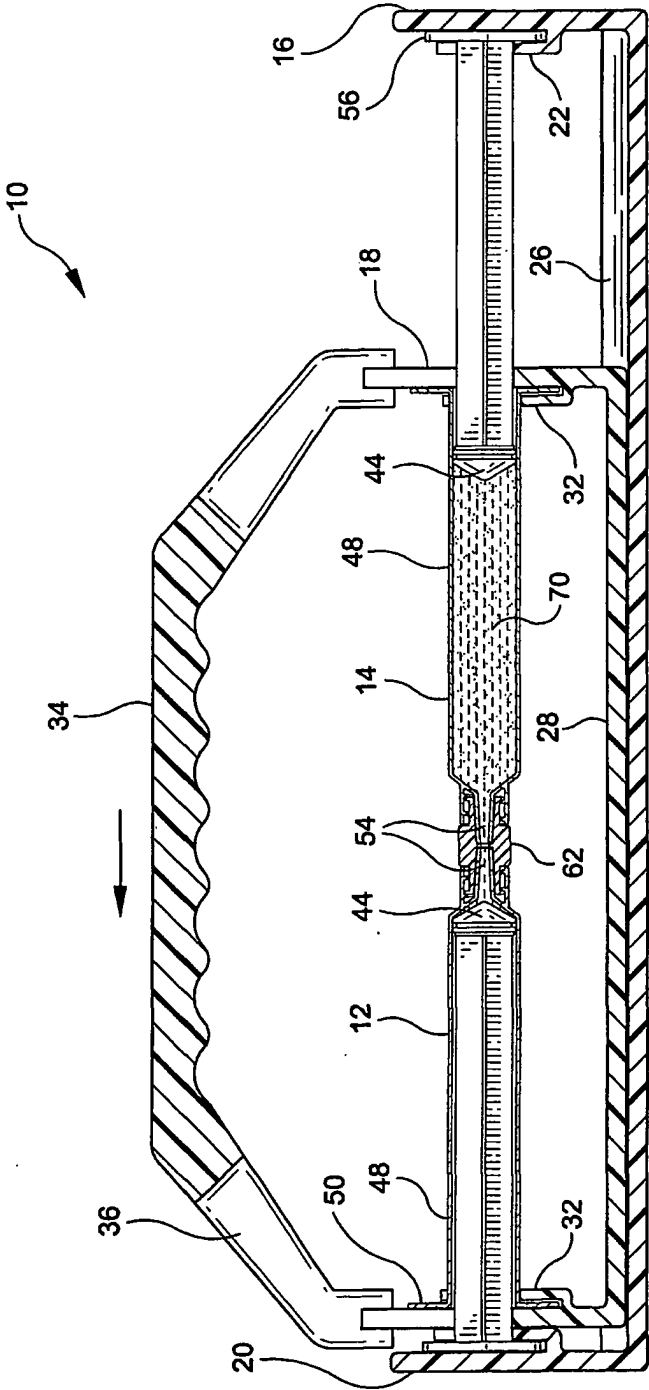
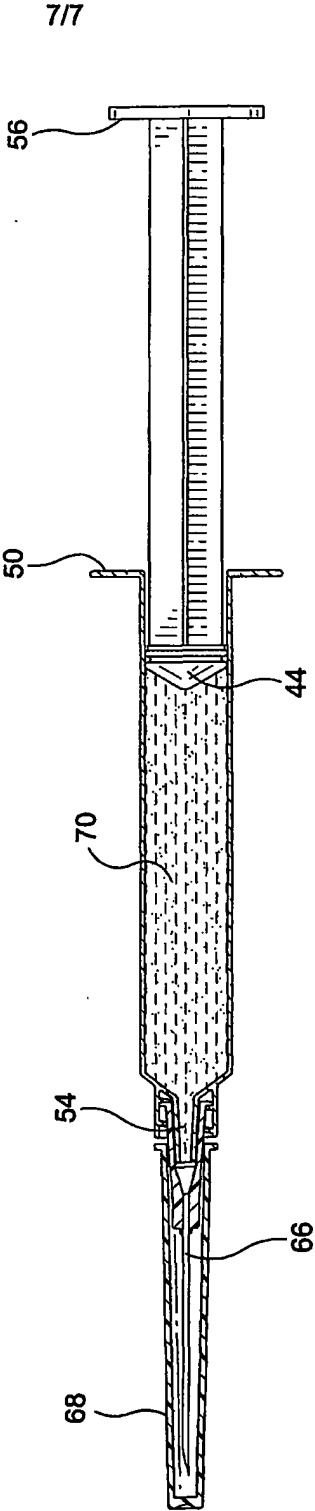


FIG. 8



International application No.
PCT/US02/01100

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :B01F 5/06, 5/12; A61M 37/00

US CL :366/268, 130, 332, 334; 604/82, 84

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 366/268, 130, 332, 333, 334; 604/82, 84, 90, 91; 206/219

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,035,820 A (TOOD et al) 22 May 1962. See entire document.	1-16
Y	US 5,957,166 A (SAFABASH) 28 September 1999. See entire document.	1-16
Y	US 5,908,054 A (SAFABASH et al) 01 June 1999. See entire document.	1-16
Y	US 4,743,229 A (CHU) 10 May 1988. See entire document.	1-16
Y	US 4,463,875 A (TEPIC) 07 August 1984. See entire document.	1-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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